

National Cancer Institute  
Institutional Review Board

**AGENDA**  
**August 10, 2015**  
1:00 – 5:00 pm  
10 CRC/3-1608

- 1. Review of Draft Minutes, July 27, 2015**
- 2. Announcements**
- 3. Old Business**
- 4. New Business**
- 5. Problem Report Forms**
- 6. Other Expedited Actions**
- 7. Continuing Reviews**
- 8. Response to Stips** P142109, "A Phase 1/2 Proof-of-Concept Study of the Combination of ACP-196 and ACP-319 in Subjects with B-cell Malignancies" - Mark Roschewski, PI
- 9. Response to Stips** 09-C-0082-Z, "Assessment of the Safety and Feasibility of Administering T cells Expressing an anti-CD19 Chimeric Antigen Receptor to Patients with B-cell Lymphoma" - Steve Rosenberg, PI
- 10. Amendment** 15C0050-A, "A Phase 2 Pilot Study of BMN 673 (Talazoparib), an Oral PARP Inhibitor, in Patients with Deleterious BRCA1/2 Mutation-Associated Ovarian Cancer who have had prior PARP Inhibitor Treatment " - Jung-Min Lee, PI
- 11. Amendment** 14C0090-B, "A Phase 2 Open-Label Study to Evaluate the Efficacy and Safety of VT-464 in Patients with Metastatic Castration Resistant Prostate Cancer Who Have Previously Been Treated with Enzalutamide" - Ravi Madan, PI
- 12. Amendment** 11C0221-L, "Carfilzomib, Lenalidomide, and Dexamethasone in Newly Diagnosed Multiple Myeloma: Clinical and Correlative Phase II Study" - Mark Roschewski, PI
- 13. Initial Review** P152327, "Care of the Prostate Cancer Patient and Prospective Procurement of Prostate Cancer Tissue" - Peter Pinto, PI